Attachment 21

Altria
Altria Client Services

Paige C. Magness
Senior Vice President
Regulatory Affairs

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Via Electronic Submission

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-N-3065 (84 Fed. Reg. 42, 754, August 16, 2019) – Comments on "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements Proposed Rule"

Altria Client Services LLC ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA") and Sherman Group Holdings, LLC and its subsidiaries ("Nat Sherman")[1] submits these comments to the U.S. Food and Drug Administration ("FDA" or the "Agency") in response to its Proposed Rule on Required Warnings for Cigarette Packages and Advertisements ("Proposed Rule").[2]

We appreciate the opportunity to provide our views and look forward to continuing to engage with FDA. If you have any questions, please feel free to contact me.

Sincerely,

Paige C. Magness

Attachments

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[1] PM USA and Nat Sherman are wholly-owned subsidiaries of Altria Group, Inc. ("Altria"). PM USA manufactures cigarettes and is licensed to sell and distribute IQOS® and HeatSticks® in the United States and Nat Sherman sells premium cigars and manufactures and sells super premium cigarettes. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA and Nat Sherman.

[2] 84 Fed. Reg. 42,754 (proposed August 16, 2019) (to be codified at 21 C.F.R. pt. 1141).

Altria Client Services LLC
2325 Bells Road
Richmond, Virginia 23234
(804) 335-2353
Paige.C.Magness@altria.com

EXECUTIVE SUMMARY

Government-mandated health warnings have been required to appear on cigarette packages for more than 50 years and on cigarette advertisements for more than 45 years. Today, cigarette smoking is at an all-time low. PM USA and Nat Sherman believe that adult smokers should have the right to make informed choices about the use of tobacco products and that there should be a single, consistent public health message about the risks of smoking that should help guide these choices.

While we recognize the need for health warnings on cigarette packages and advertisements, FDA's second attempt at a regulation requiring graphic health warnings suffers from a number of fatal flaws. Our comments are organized into four sections. The first section urges FDA to exempt HeatSticks®, which are unique non-combustible "cigarettes" designed for use with the IQOS® tobacco heating system, from this rule. Although those products do not eliminate all health risks associated with tobacco and nicotine use, they are materially different from traditional combustible cigarettes, and, we believe, also significantly less harmful. Indeed, this Agency has already determined that the marketing of this product is "appropriate for the protection of public health." The second section raises practical concerns impacting the implementation of the Proposed Rule. The third section explains that without substantial changes, the Proposed Rule would violate the Administrative Procedure Act ("APA") on multiple grounds. The fourth, and final, section demonstrates that the text and graphic warnings proposed by this rule would violate free speech protections guaranteed by the First Amendment of the U.S. Constitution.

To guide the Agency in the materials that follow, we provide an overview of the four sections listed above.

Any Final Rule Should Exempt HeatSticks® from the Proposed Graphic-Warnings Requirements

IQOS® is an electronic device that heats tobacco in HeatSticks® to generate nicotine-containing aerosol without combustion, fire, ash, or smoke. After a thorough science-based review, FDA granted marketing authorization for IQOS® and HeatSticks® in April 2019, concluding that marketing those products would be "appropriate for the protection of public health."[1] FDA based this conclusion on its rigorous assessment of the critical differences between HeatSticks® and traditional, combustible cigarettes. FDA noted several material differences—among them, that HeatSticks® do not combust or produce smoke; that HeatSticks® reduce exposures to harmful and potentially harmful constituents ("HPHCs"); that HeatSticks® are "likely to lead to less risk of tobacco-related diseases;" and that HeatSticks® have the potential to benefit current smokers who switch to them.[2] Because HeatSticks® qualify as a "cigarette" as that term is defined in the Federal Cigarette Labeling and Advertising Act ("FCLAA"),[3] FDA's Marketing Order requires HeatSticks® packaging and advertising to bear the rotating Surgeon General's warnings required by that Act. Significantly, however, based on the Agency's recognition of significant differences

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[1] Attachment 1, CTP Technical Project Lead Review (TPL) Review of IQOS PMTA: PM0000424, PM0000425, PM0000426, and PM0000479 (April 29, 2019) ("IQOS® TPL Review") at 12, *available at* https://www.fda.gov/media/124247/download.

[2] *Id.* at 11-12, 92, 95; *see also id.* at 64-65.

[3] 15 U.S.C. § 1332(1).

formats and either exemptions or alternative fonts and images for small-sized advertisements.

- Finally, to account for the interdependent chain of events necessary to implement graphic health warnings, FDA should extend or toll the implementation deadline.

A. FDA should reduce the number of required graphic warnings to 12 or 9

The Proposed Rule requires manufacturers to randomly display 13 graphic images, each associated with one of 12 textual warning label statements, on their cigarette packages and advertisements.[51] FDA invites comment on "whether and how the number of final required warnings selected would affect the *random and equal* display and distribution of the required warnings on packages and the quarterly rotation of the required warnings in advertisements."[52] As explained below, manufacturers cannot satisfy the "random and equal" requirement for 13 different warnings without drastic and uncertain changes to packaging production.[53] Thirteen is both an odd and prime number. As such, it is fundamentally incompatible with industry-wide printing practices and the random and equal distribution requirements of proposed § 1141.10(g) for cigarette packages. We urge FDA to reduce the number of graphic warnings to 12 or 9.

1. Manufacturers cannot randomly and equally display and distribute 13 warnings on cigarette packages.

Standard industry practices print graphics in grid layouts. When package designers plan a print run, they arrange the desired package graphics in a grid based on the package style and type of printing press used.[54] Each rotation of the press cylinder prints the grid pattern onto packaging materials.[55] The grid pattern depends on the technical capabilities of the printing press, which are fixed.[56] We use a handful of grid layouts, depending on type of press and package being produced.[57]

Standard grid layouts cannot accommodate a requirement to print equal quantities of 13 warnings. Our 32-inch press for hard packs illustrates this conundrum.[58] This press prints in an 8x3 layout, resulting in 24 total impressions (Figure 1).

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[51] 84 Fed. Reg. at 42,797.
[52] *Id*. at 42,784 (emphasis added).
[53] *See* Attachment 3, Declaration of Yvonne DeVerry ("DeVerry Decl.") ¶ 13.
[54] *Id*. ¶ 14.
[55] *Id.*
[56] *Id*. ¶ 15.
[57] PM USA uses two layouts for hard pack printing presses. The 26-inch presses are arranged with six lanes and 3 impressions per lane (6x3). The 32-inch presses print 8 lanes with 3 impressions per lane (8x3). We currently use a 2x 2 and a 1x2 layout for cartons. We currently use 9x5 and 8x5 layouts for soft pack presses.
[58] Similar outcomes result from all layouts used. The 8x3 layout is being used as an illustrative example. Attachment 3, DeVerry Decl. ¶ 18.

the literature determined that "[c]onsumers suffer from a pervasive lack of knowledge about and understanding of the negative health consequences of smoking," including findings that 33% of sampled adult smokers "did not know that cigarettes were a proven cause of cancer" and that "people underestimated the percent of people diagnosed with lung cancer who would die from the condition."[106] These findings fail to explain why FDA did not include warnings about lung cancer, yet focused on heart disease and COPD, and raise questions about FDA's criteria for selecting particular conditions to highlight.

In a similar vein, FDA provided no explanation for why it chose to develop warnings about certain less-known conditions as opposed to other less-known conditions with worse survival rates or greater incidences. The below table and figure (Table 1 and Figure 8), show a list of conditions, derived from Surgeon General Reports from 2004 and 2014, the relative risk that a current smoker will contract the condition (compared to a non-smoker), adult prevalence of the condition, and the projected five-year survival rate for the condition. FDA noted that "consumers are largely unaware of the negative health consequences of cigarette smoking not mentioned in current warnings as well as more specific information about the negative health effects and their mechanisms."[107] But FDA's decision to focus on less-known health consequences does not explain why, even at the earliest stages of FDA's studies, FDA zeroed in on some types of cancer (like mouth and throat cancer, head and neck cancer, and bladder cancer) but failed to test other types of cancer (like colorectal cancer, pancreatic cancer, cervical cancer, liver cancer, or kidney cancer) that are more prevalent or more fatal.

[106] *Id.* at 42,761.
[107] *Id.* at 42,766.

Table 1: Summary Table of Diseases Causally Linked to Smoking by the Surgeon General in 2004 or 2014 Reports with Relative Risks, Prevalence Estimation, and 5-Year Survival

Disease	Included as graphic warning?	Relative risk (current smokers)	Adult prevalence[1]	5-year survival %[2]
Combined Head and Neck Cancer (Women)	**Yes**	**12.96** (Freedman, Abnet, Leitzmann, Hollenbeck, & Schatzkin, 2007)	**142,277** (SEER, 2018a)	**66%** (Peng, Grogan, & Wang, 2014)
Combined Head and Neck Cancer (Men)	**Yes**	**5.45** (Freedman et al., 2007)	**340,105** (SEER, 2018a)	
Trachea, Bronchus, and Lung Cancer (Men and Women)	**No**	**10.92** (Jayes et al., 2016)	**520,195** (SEER, 2018a)	**18.1%** (SEER, 2018b)
COPD	**Yes**	**4.01** (Jayes et al., 2016)	**16,800,000** (BRFSS, 2018)	**41.5%** (Foucher et al., 1998)
Bladder Cancer	**Yes**	**3.14** (van Osch, Jochems, van Schooten, Bryan, & Zeegers, 2016)	**686,874** (SEER, 2018a)	**77.3%** (SEER, 2018b)
Atherosclerotic Peripheral Vascular Disease	**Yes**	**2.71** (Lu, Mackay, & Pell, 2014)	**8,500,000** (Allison et al., 2007)	**66%** (Criqui et al., 1992)
Stroke	**Yes**	**2.52** (Robbins, Manson, Lee, Satterfield, & Hennekens, 1994)	**7,000,000** (Roger et al., 2011)	**~55%**[A] (Aparicio, 2017)
Coronary Heart Disease	**Yes**	**2.42** (Hackshaw, Morris, Boniface, Tang, & Milenković, 2018)	**16,300,000** (Roger et al., 2011)	**~74%**[B] (Mukamal, 2001)
Aortic Aneurysm	**No**	**2.41** (Cornuz, Sidoti Pinto, Tevaearai, & Egger, 2004)	**1,340,000** (Hirsch et al., 2006)	**90.3%** (Mani, Bjorck, Lundkvist, & Wanhainen, 2009)
Age-related Macular Degeneration (AMD)	**Yes**	**2.35** (Thornton et al., 2005)	**2,070,000** (National Eye Institute, 2019)	**100%**
Cataracts (nuclear)	**Yes**	**2.24** (Christen et al., 1992)	**20,500,000** (Congdon et al., 2004)	**100%**

Disease	Included as graphic warning?	Relative risk (current smokers)	Adult prevalence[1]	5-year survival %[2]
Rheumatoid Arthritis	**No**	**2.02** (Di Giuseppe, Discacciati, Orsini, & Wolk, 2014)	**66,800,000** (BRFSS, 2018)	**100%**
Pancreas Cancer	**No**	**1.9** (Ordonez-Mena et al., 2016)	**64,361** (SEER, 2018a)	**8.2%** (SEER, 2018b)
Periodontitis	**No**	**1.85** (Leite, Nascimento, Scheutz, & López, 2018)	**64,700,000** (Eke et al., 2015)	**98%**[C] (Kim, Baker, Davarian, & Crimmins, 2013)
Cervix Cancer	**No**	**1.83** (Gandini et al., 2008)	**224,655** (SEER, 2018a)	**67.1%** (SEER, 2018b)
Asthma	**No**	**1.61** (Jayes et al., 2016)	**24,100,000** (BRFSS, 2018)	**90%**[D] (Ringbaek, Seersholm, & Viskum, 2005)
Stomach Cancer	**No**	**1.6** (Surgeon General (SG), 2004)	**94,587** (SEER, 2018a)	**30.6%** (SEER, 2018b)
Liver Cancer	**No**	**1.56** (Gandini et al., 2008)	**66,233** (SEER, 2018a)	**17.6%** (SEER, 2018b)
Acute Myeloid Leukemia	**No**	**1.52** (Colamesta et al., 2016)	**61,048** (SEER, 2019)	**26.9%** (SEER, 2018b)
Kidney and Ureter Cancer	**No**	**1.52** (Gandini et al., 2008)	**471,919** (SEER, 2018a)	**74.1% & 46.5%**, respectively (SEER, 2018b)
Erectile Dysfunction	**Yes**	**1.5** (Bacon et al., 2006)	**18,000,000** (Selvin, Burnett, & Platz, 2007)	**100**%
Diabetes (type 2)	**Yes**	**1.37** (SG Report, 2014)	**27,700,000** (BRFSS, 2018)	**~72%**[B] (Mukamal, 2001)
Colorectal Cancer	**No**	**1.2** (Ordonez-Mena et al., 2016)	**1,300,518** (SEER, 2018a)	**64.9%** (SEER, 2018b)

Notes: [1]Cancer prevalence is defined as first per site in the past 39 years. BRFSS estimates for adults assume an adult (18+) population of 253,900,000 and older adult (65+) population of 52,300,000 based on 2018 mid-year intercensal estimates. [2]Cancer survival is 5-year relative survival percent. Relative survival is the percent of the diseased population that are alive divided by the general population alive after 5 years. Some chronic diseases have absolute survival reported when a relative survival estimate was not attained. Some conditions (cataracts, age-related macular degeneration, erectile dysfunction, and rheumatoid arthritis) are assumed to not contribute to mortality and have 100% relative survival. [A]Absolute survival. [B]Absolute survival. [C]Absolute survival. [D]Men, absolute survival (Denmark). No applicable U.S. percentage found.

Figure 8: Data Visualization of Conditions Caused by Smoking, by Relative Risk and Five-Year Survival

Source: See Table 1.

Third, FDA provided no evidence to support why it selected particular graphics to illustrate the textual warnings. Nor did FDA explain whether it considered alternative graphics to illuminate the same concepts or why it chose the selected graphics over others that could have illustrated the same text. The Proposed Rule states that FDA conducted a series of focus groups to examine "what factual information the images conveyed to participants about the negative health consequences of cigarette smoking in the absence of paired textual warning statements, as well as how concordant participants considered the images to be when paired with potential textual warning statements."[108] FDA used results from this qualitative research to select graphics used

[108] *Id.* at 42,770.

capability in order to capture how well Americans understand what they hear and what they are told."[132] Further, the majority of FDA-cited studies do not systematically test the text and graphic alone and in combination, making it impossible to understand the unique contribution of either. To our knowledge, only a few studies systematically tested graphic health warnings (e.g., Refs. 12 and 77). Byrne et al., 2017 did not find any statistically significant differences in risk beliefs between text-only warnings and graphic warnings with the same text (Ref. 77).[133] That study did not include measures of knowledge level or understanding; rather, participants agreed or disagreed with a list of known health effects based on a read-and-recall task. Mutti et al. 2013 (Ref. 12) used a similar task to evaluate health beliefs, with no measure of comprehension, and did not test for differences between the text-only and text plus graphic conditions. FDA's cited literature does not establish that graphics contribute to understanding or comprehension beyond the text alone.

Finally, some studies that FDA cites attempted to measure real-world impact of graphic health warnings on behavior and intentions, but those studies are also faulty.[134] They lack data to correlate intentions to longer-term number of quit attempts, future purchase behavior, reduction in cigarettes per day, etc., all of which are direct measures of smoking behavior (Refs. 12, 77, and 81). Brewer et al. (2019) (Ref. 84) measured quit attempts over a 4-week period, but the authors acknowledged that longer-term effects cannot be extrapolated. "Future studies should evaluate relationships of self-reported effectiveness rankings with recall and behavior change (i.e., smoking behaviors, changes in risk perceptions) to determine how this construct relates to more complex processes and behavior" (Mercincavage et al., 2018). Again, this evidence provides no sound basis for FDA's decision to impose the proposed warnings as a means of addressing the health consequences of smoking.

C. FDA ignored contrary scientific evidence

Even setting aside the weakness of the evidence FDA invokes, FDA has not provided a legally sufficient basis for the rule. That is because FDA has failed to adequately address a litany of evidence that undermines virtually every premise of the Proposed Rule.

First, FDA did not adequately address contrary evidence indicating that graphic warnings do *not* meaningfully influence consumer knowledge regarding the consequences of smoking. FDA essentially ignores findings from U.S.-based studies—the most relevant evidence—showing that graphic warnings are ineffective in improving consumer comprehension regarding the health consequences of smoking. Indeed, FDA neglected to cite several U.S.-based studies that demonstrated little or no contribution of added graphics to textual warning messages (Bekalu et al., 2019; Shadel et al., 2019; Skurka et al., 2019; Van Dessel, Smith, & De Houwer, 2018).

Other U.S. studies further undercut FDA's conclusion that graphic warnings increase knowledge and accurate health beliefs concerning the consequences of smoking. For example, Robinson and Killen (Ref. 62) reported a paradoxical, significant increase in smoking behavior from baseline to three-month follow-up in high-school students with higher awareness of pack

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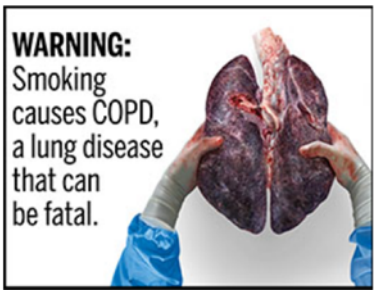
[132] IOM Roundtable on Health Literacy Workshop, Measures of Health Literacy: Workshop Summary (2009) https://www.ncbi.nlm.nih.gov/books/NBK45384/pdf/Bookshelf_NBK45384.pdf.
[133] Based on our review of Ref. 77.
[134] Based on our review of Refs. 12, 77 and 81.

covered by a large cataract." 84 Fed. Reg. at 42,777.	• Contrary to FDA's stated criteria for image selection, the text and image are not "concordant." 84 Fed. Reg. at 42,765. The text of the image indicates that smoking can lead to blindness. Yet the picture does not clearly indicate that the individual depicted is blind. And in fact, the individual appears to *not* be blind. Losing sight in one eye is tragic, but it does not meet the definition of blindness. • The warning—when viewed as part of a rotational sequence of warnings that all get equal distribution—is misleading because it suggests to consumers that their risk of exposure to smoking-attributable cataracts and blindness is the same as or greater than their risk of exposure to other, more-prevalent smoking-related conditions that other warnings depict, such as COPD. *See supra* Table 1. • Further, the warning emphasizes a chronic, non-fatal condition. This is not to diminish the seriousness of cataracts. But FDA omits from the warnings other conditions with high mortality rates, such as trachea, bronchus, and lung cancer, pancreas cancer, stomach cancer, liver cancer, and acute myeloid leukemia, raising further questions about whether the warnings directly advance FDA's stated educational aims. *See supra* Fig. 8. Finally, the warning emphasizes a condition—blindness—that occurs in only a small minority of cases (0.48%) of cataracts.[211]
 FDA Description: "The image shows gloved hands holding a pair of diseased, darkened lungs removed from a smoker	• The warning impermissibly seeks to advance FDA's anti-smoking message by "evok[ing] an emotional response in consumers." *R.J. Reynolds*, 696 F.3d at 1216. The selected image of blood-covered hands holding bloody, diseased lungs that appear to have been taken from a deceased person is intended to shock and disturb viewers with its goriness or to generate fear about the prospect of death and having one's lungs removed postmortem. • The selected image of blood-covered hands holding bloody, diseased lungs does not convey "purely factual information." The image does not provide any information not already contained in the text, such as, for

[211] According to the National Eye Institute, the number of cataracts cases in the U.S. in 2010 was 24,408,000. https://nei.nih.gov/learn-about-eye-health/resources-for-health-educators/eye-health-data-and-statistics. If it is assumed that blindness is represented among the incident cases of cataracts, 0.48% of cataracts cases result in blindness in the U.S.